

C. Remarks

The claims are 56, 57, 60, 64, 66-68 and 74-83, with claims 74 and 83 being independent. Claim 58 has been cancelled without prejudice or disclaimer. Claim 83 has been amended to clarify the invention; Applicant submits that the amendment is supported by the application as originally filed and, therefore, does not constitute new matter.

Reconsideration of the pending claims is respectfully requested.

The Examiner objected to the abstract due to certain informalities.

Applicant has amended the abstract in order to address the Examiner's concerns.

Accordingly, removal of the objection is respectfully requested.

The Examiner objected to the specification due to certain informalities.

Claim 58 has now been cancelled. Accordingly, the objection is moot and should be removed.

Claims 56-58, 60, 64, 66-68 and 74-83 stand rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. Applicants respectfully traverse this rejection. First, claim 58 (as noted above) has been cancelled. Second, with regard to the term "purified state", Applicant respectfully disagree with the Examiner's position that the term in question is a relative one. In fact, Applicant submits that one of ordinary skill in this art would readily appreciate that a polymer in the purified state, according to the present invention, is one which is both off-white to white in color and contains one or more metals in cationic form, wherein the one or more metals have a concentration up to 10 ppm. Each of these requirements is set forth in detail in the specification as filed. Accordingly, withdrawal of the §112 rejection is respectfully requested.

Claims 56-58, 60, 64, 66-68 and 74-83 stand rejected under 35 U.S.C.

§103(a) as being obvious over Bodmer (U.S. Patent No. 5,538,739) in view of Brich (GB 2,145,422) and Reiners (U.S. Patent No. 4,879,402) or Bendix (U.S. Patent No. 4,810,775) and further in view of Eliot (A Manual of Inorganic Chemistry, 1876) and as evidenced by Sigworth (J. Am. Water Works Ass'n., 1972). Applicant respectfully traverses this rejection.

At the outset, Applicant incorporates by reference herein the arguments advanced in previous responses. Next, Applicant would like to draw the Examiner's attention to a point that may have been overlooked in the recent prosecutorial exchanges. Independent claim 74 is directed to a pharmaceutical composition. That pharmaceutical composition has a very specific composition, namely (a) a polylactide polymer in a purified state and (b) a hydrophilic or lipophilic drug. Importantly, the polylactide polymer in a purified state is an ester of a polyol containing at least three hydroxyl groups and is off-white to white in color; in addition, the polylactide in a purified state contains one or more metals in cationic form, where the one or more metals have a concentration up to 10 ppm.

The simple fact is that no combination of the cited references discloses or suggests such a pharmaceutical composition. At least with regard to the claimed metal concentration, the Examiner appears to be making the case that such a claim feature would be inherent in the polylactide polymers of the cited art since it would have been obvious to purify using activated charcoal (two points which Applicant expressly does not concede). However, as set forth in MPEP §2163.07:

“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

In this case, the Examiner is attempting to establish by possibility that a polylactide polymer of the cited art would have the claimed metal concentration. However, such a feature is not a given. Accordingly, Applicant respectfully submits that the cited combination of references fails to disclose or suggest all of the claim features and therefore requests withdrawal of the §103 rejection.

Claim 83 stands rejected under 35 U.S.C. §103(a) as being obvious over Bendix in view of Sigworth. Applicant respectfully traverses this rejection.

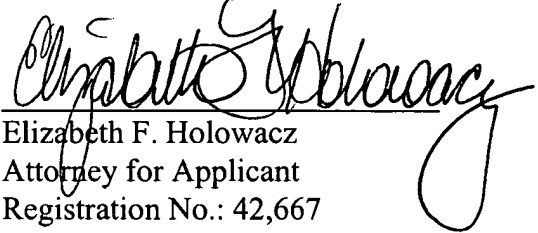
The present invention as set forth in amended claim 83 is directed to a method of removing tin from a polylactide polymer comprising the step of contacting a polylactide polymer with activated charcoal to reduce tin concentration. The cited combination of references is deficient in certain key respects insofar as each of the two references fails to remedy the other’s deficiency. Bendix may teach that activated charcoal

can be used as a purification stage prior to an actual purification precipitation, but, as noted by the Examiner, Bendix contains no disclosure related to such a purification stage to remove tin. Sigworth, on the other hand, teaches that tin is readily adsorbed from a water sample onto carbon, but fails to teach or suggest that such a mechanism will work for a polylactide polymer. In fact, given Sigworth's statement that "it is very difficult in a given instance to predict what will happen" (at page 390) when using activated charcoal to purify in certain settings, Applicant submits that there was no reasonable likelihood of success in using activated charcoal to reduce tin concentration in a polylactide polymer. For at least these reasons, Applicant respectfully requests withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue is earnestly requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100 or at the below listed address. All correspondence should continue to be directed to Novartis, Corporate Intellectual Property, One Health Plaza 104/3, East Hanover, NJ 07936-1080.

Respectfully submitted,



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